JUN - 7 2004

Exhibit IV: 510(k) Summary

K041385

Schick Computed Oral Radiology System

Common/Classification Name: Solid State X-ray Imager
21 CFR892.1650

Schick Technologies, Inc.
30-00 47th Avenue
Long Island City, NY 11101
718-937-5765, 718-937-5962 (FAX)
Contact: Daniel Michaeli, Prepared: May 24, 2004

A. Legally Marketed Predicate Devices

The original Computed Oral Radiology System notification was cleared on January 31st, 1994 (K933455). The device and its predicate are small digital imaging receptors that may be used in place of dental x-ray film.

B. Modification Description

The new control mechanism differs from the predicate in that image acquisition may additionally be triggered through a hardwire to an x-ray tube. This modification allows for a quicker x-ray response time and may improve ergonomics as it eliminates the need for a standalone remote module.

The existing firmware has been altered to support the modified and additional hardware. The new remote module may be housed within a specified x-ray source. The modification in no way effects the fundamental technology governing image acquisition.

C. Indications for Use

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage. This device modification in no way alters the indications for use of this machine beyond what was originally cleared in K933455.

D. Substantial Equivalence Summary

A risk analysis established the areas of concern. The principal risk is unintended x-ray exposure. These areas have been evaluated following bench, and third-party safety testing. All validation activities have demonstrated that the

predetermined acceptance criteria were met. Where appropriate, warnings have been incorporated within the user manual.

E. Conclusions

Schick Technologies has demonstrated through a risk analysis and validation studies that the device modification is substantially equivalent to the already cleared and marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Mr. Daniel Michaeli
Director of Science Development
Schick Technologies, Inc.
30-00 47th Avenue
LONG ISLAND CITY NY 11101

Re: K041385
Trade/Device Name: Computed Oral Radiology System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 MQB
Dated: May 24, 2004
Received: May 25, 2004

Dear Mr. Michaeli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041385

Device Name: Computed Oral Radiology System

Indications For Use:

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041385